[11443/158]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	Examiner: John P. Leubecker
Michael P. Whitman	
For: SELF-CONTAINED STERILIZABLE ENDOSCOPE	
	Art Unit: 3739
Filed: September 30, 2003	
Serial No.: 10/676,046	

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Commissioner for Patents
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I hereby certify that this correspondence is being electronically transmitted to the United States Patent and Trademark Office via the Office electronic filing system on ***May 18, 2009***.
Signature: /Josephine B. Hardy/
Josephine B. Hardy

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

SIR:

On October 16, 2008, Appellant submitted a Notice of Appeal from the last decision of the Examiner contained in the Final Office Action dated April 16, 2008 in the above-identified patent application.

In accordance with 37 C.F.R. § 41.37, this brief is submitted in support of the appeal of the rejections of claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82. For at least the reasons set forth below, the final rejections of claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82 should be reversed.

1. REAL PARTY IN INTEREST

The real party in interest in the present appeal is POWER MEDICAL INTERVENTIONS, INC. of Langhorne, Pennsylvania, which is the assignee of the entire right, title and interest in and to the present application.

2. RELATED APPEALS AND INTERFERENCES

There are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., "which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal."

3. STATUS OF CLAIMS

Claims 5, 9, 33, 35, 59, and 65 have been canceled.

Claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82 are pending.

Claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of International Patent Application No. WO 93/15648 ("Wilk et al."), U.S. Patent No. RE36,434 ("Hamlin et al."), and U.S. Patent No. 4,884,133 ("Kanno et al.").

A copy of the appealed claims, *i.e.*, claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82, is attached hereto in the Claims Appendix.

4. STATUS OF AMENDMENTS

In response to the Final Office Action dated April 16, 2008, Appellant submitted a "Reply Under 37 C.F.R. § 1.116" ("the Reply") on October 16, 2008. The Reply included proposed amendments to claims 1, 4, 6, 8, 29, 34, 36, 38, 56, 63, 64, 66, and 67, and canceled claims 33 and 65. The Advisory Action dated October 31, 2008 indicates that the proposed claim amendments would be entered. As such, it is Appellant's understanding that the proposed claim amendments have been entered, and the claims as included in the annexed "Claims Appendix" reflects entry of the proposed claim amendments.

5. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 1 relates to a surgical system. *Specification*, page 4, lines 22 to 23. Claim 1 recites that the system includes a shaft 12 having a distal end 12a and a proximal end 12b, an interior of the shaft 12 having a fluid-tight seal from the environment at the distal end 12a and the proximal end 12b so as to be sterilizable for re-use. *Specification*, page 5, lines 6 to 9. Claim 1 recites that the system includes an image capture device 28 configured to receive image data from the distal end 12a of the shaft 12. *Specification*, page

5, lines 21 to 22. Claim 1 recites that the system includes a light-emitting diode 26 configured to provide light at the distal end 12a of the shaft 12. *Specification*, page 8, lines 1 to 4. Claim 1 recites that the image capture device 28 and the light-emitting diode 26 are mounted at the distal end 12a of the shaft 12 and fluid-tightly sealed from the environment by the shaft 12 so as to be sterilizable for re-use. *Specification*, page 6, lines 8 to 10.

Independent claim 29 relates to a surgical system. *Specification*, page 4, lines 22 to 23. Claim 29 recites that the system includes a shaft 12 having a distal end 12a and a proximal end 12b, wherein an interior of the shaft 12 has a fluid-tight seal from the environment at the distal end 12a and the proximal end 12b so as to be sterilizable for re-use. *Specification*, page 5, lines 6 to 9. Claim 29 recites that the system includes an image capture device 28 configured to receive image data from the distal end 12a of the shaft 12. *Specification*, page 5, lines 21 to 22. Claim 29 recites that the system includes a light-emitting diode 26 configured to provide light at the distal end 12a of the shaft 12. *Specification*, page 8, lines 1 to 4. Claim 29 recites that the image capture device 28 and the light-emitting diode 26 are mounted at the distal end 12a of the shaft 12 and fluid-tightly sealed from the environment by the shaft 12 so as to be sterilizable for re-use. *Specification*, page 6, lines 8 to 10.

Independent claim 56 relates to a surgical system. *Specification*, page 4, lines 22 to 23. Claim 56 recites that the system includes a shaft 12 having a proximal end 12b and a distal end 12a, wherein an interior of the shaft has a fluid-tight seal from the environment at the proximal 12b and at the distal end 12a so as to be sterilizable for re-use. *Specification*, page 5, lines 6 to 9. Claim 56 recites that the system includes an image capture device 28 configured to receive image data from the distal end 12a of the shaft 12. *Specification*, page 5, lines 21 to 22. Claim 56 recites that the system includes a light-emitting diode 26 configured to provide light at the distal end 12a of the shaft 12. *Specification*, page 8, lines 1 to 4. Claim 56 recites that the system includes a control module 14 coupled to the proximal end 12b of the shaft 12. *Specification*, page 5, lines 20 to 21. Claim 56 recites that the system includes a power module 50 coupled to the control module 14, the power module 50 configured to drive at least one drivable component housed in at least one of the shaft 12, the control module 14 and the power module 50. *Specification*, page 12, lines 20 to 21; and page 14, lines 7 to 12. Claim 56 recites that the system includes at least one power source 27a, 27b integrally housed in at least one of the shaft 12, the control module 14 and the power module 50. *Specification*, page 6, lines 17 to 19, and 23 to 26; and page 7, lines 12 to 15. Claim 56 recites that the image capture device 28 and the light-emitting diode 26 are mounted at the

distal end 12a of the shaft 12 and fluid-tightly sealed from the environment by the shaft 12 so as to be sterilizable for re-use. *Specification*, page 6, lines 8 to 10.

6. GROUND OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82 are patentable under 35 U.S.C. § 103(a) over the combination of Wilk et al., Hamlin et al., and Kanno et al.

7. ARGUMENT

Claims 1 to 4, 6 to 8, 10 to 32, 34, 36 to 58, 60 to 64, and 66 to 82 stand rejected under 35 U.S.C. § 103(a) as unpatentable over the combination of Wilk et al., Hamlin et al., and Kanno et al. It is respectfully submitted that the combination of Wilk et al., Hamlin et al., and Kanno et al. does not render unpatentable the present claims for at least the following reasons.

As set forth above, claim 1 relates to a surgical system that includes, *inter alia*, the features that ***a light-emitting diode is mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use***. Claims 29 and 56 include features analogous to those of claim 1.

It is respectfully submitted that the combination of Wilk et al., Hamlin et al., and Kanno et al. does not disclose, or even suggest, that ***a light-emitting diode is mounted at a distal end of a shaft and fluid-tightly sealed from the environment by the shaft***.

The Office Action dated July 16, 2007 admits at page 5 that "Wilk et al. in view of Hamlin et al. . . . fails to specify the nature of the light source." Indeed, the combination of Wilk et al. and Hamlin et al. fails to disclose or suggest a light emitting diode, much less that ***a light-emitting diode is mounted at a distal end of a shaft and fluid-tightly sealed from the environment by the shaft***. Thus, the Examiner has conceded that the combination of Wilk et al. and Hamlin et al. does not disclose or suggest all of the features recited in claims 1, 29 and 56.

The Final Office Action contends at paragraph 3 that it would be obvious to use a light-emitting diode of Kanno et al. in the device of Wilk et al. However, neither the light source illustrated in Figure 1 of Wilk et al. nor the light source 160 illustrated in Figure 7 of Wilk et al., if replaced by a light-emitting diode, would be ***mounted at the distal end of a shaft and fluid-tightly sealed from the environment by the shaft***. Further, regarding the Final Office Action's suggestion to replace the optical fiber of Wilk et al. with a light-

emitting diode, it is unclear why or how one of ordinary skill in the art would replace an optical fiber that is attached to a light source with a light-emitting diode, as opposed to replacing the light sources 34 and/or 160 with a light-emitting diode.

Moreover, it is respectfully submitted that the combination of Wilk et al., Hamlin et al., and Kanno et al. fails to disclose, or even suggest, that *a light-emitting diode is mounted at a distal end of a shaft and* ***fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use***.

In this regard, Wilk et al. ***teaches away*** from this feature of claims 1, 29 and 56. For example, Wilk et al. explicitly states that "[t]here is ***no need to subject optical guide member 20 to sterilizing*** and cleaning operations which may damage the optical guide and eventually wear it down." Page 9, lines 7 to 10 (emphasis added). Thus, Wilk et al. specifically seeks to avoid sterilizing its optical guide member 20 due to potential damage and wear. Further, Hamlin et al. also ***teaches away*** from this feature of claims 1, 29 and 56. For example, Hamlin et al. explicitly seeks to "prevent[] contamination of the lens tube 12 and ***obviat[e] the need for sterilization*** of the lens tube 12." Col. 6, lines 8 to 9 (emphasis added). Thus, Hamlin et al. specifically seeks to obviate sterilizing its lens tube 12. In addition, Kanno et al. does not even refer to fluid-tightly sealing from the environment by the shaft, much less fluid-tightly sealing so as to be sterilizable for re-use.

As set forth in the M.P.E.P. § 2141, "[t]he key to supporting any rejection under 35 U.S.C. § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious." However, as set forth by the Supreme Court, "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Among the rationales that may support a conclusion of obviousness are: (a) combining prior art elements according to known methods to yield predictable results; (b) simple substitution of one known element for another to obtain predictable results; (c) use of known technique to improve similar devices (methods, or products) in the same way; (d) applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (e) "obvious to try" -- choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (f) known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art; and (g) some teaching, suggestion, or

motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

The Final Office Action does not even allege any of the foregoing rationales. Rather than set forth sufficient rationale for making the proposed modification, the Final Office Action merely -- and conclusorily -- refers to the statement in the Office Action of July 16, 2007, which contends at page 3 that "it would have been obvious to one of ordinary skill in the art at the time of the invention to have used LEDs for the generic 'light source' of Wilk et al."

Since the combination of Wilk et al., Hamlin et al., and Kanno et al. does not disclose, or even suggest, all of the limitations of claims 1, 29 and 56 as more fully set forth above, nor does the Final Office Action provide sufficient, articulated rationale to support the obviousness rejection, it is respectfully submitted that the combination of Wilk et al., Hamlin et al., and Kanno et al. does not render unpatentable claims 1, 29 and 56.

As for claims 2 to 4, 6 to 8, and 10 to 28, which ultimately depend from claim 1 and therefore include all of the features included in claim 1, claims 30 to 32, 34, and 36 to 55, which ultimately depend from claim 29 and therefore include all of the features included in claim 29, and claims 57, 58, 60 to 64, and 66 to 82, which ultimately depend from claim 56 and therefore include all of the features included in claim 56, it is respectfully submitted that the combination of Wilk et al., Hamlin et al., and Kanno et al. does not render unpatentable these dependent claims for at least the same reasons more fully set forth above.

In view of all of the foregoing, reversal of this rejection is respectfully requested.

8. CLAIMS APPENDIX

A "Claims Appendix" is attached hereto and appears on the eight (8) pages numbered "Claims Appendix 1" to "Claims Appendix 8."

9. EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellant in the appeal. An "Evidence Appendix" is nevertheless attached hereto and appears on the one (1) page numbered "Evidence Appendix."

10. RELATED PROCEEDINGS APPENDIX

As indicated above in Section 2, "[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., 'which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.'" As such, there are no "decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]" to be submitted. A "Related Proceedings Appendix" is nevertheless attached hereto and appears on the one (1) page numbered "Related Proceedings Appendix."

11. CONCLUSION

For at least the reasons indicated above, Appellant respectfully submits that the art of record does not disclose or suggest the subject matter as recited in the claims of the above-identified application. Accordingly, it is respectfully submitted that the subject matter as set forth in the claims of the present application is patentable.

In view of all of the foregoing, reversal of all of the rejections set forth in the Final Office Action is therefore respectfully requested.

Respectfully submitted,

Dated: May 18, 2009

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CLAIMS APPENDIX

1. A surgical system comprising:

a shaft having a distal end and a proximal end, an interior of the shaft having a fluid-tight seal from the environment at the distal end and the proximal end so as to be sterilizable for re-use;

an image capture device configured to receive image data from the distal end of the shaft;

a light-emitting diode configured to provide light at the distal end of the shaft,

wherein the image capture device and the light-emitting diode are mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use.

2. The system of claim 1, wherein the shaft is sized and configured for endoscopic insertion into a patient's body.

3. The system of claim 1, wherein the shaft is flexible.

4. The system of claim 1, wherein the light-emitting diode is part of an array of light-emitting diodes.

6. The system of claim 1, wherein the light-emitting diode, the image capture device and the shaft are, as a unit, at least one of sterilizable and autoclavable.

7. The system of claim 1, wherein the image capture device is one of a camera and a CCD.

8. The system of claim 1, further comprising a power source for providing power to the light-emitting diode, the power source located at the distal end of the shaft.

10. The system of claim 1, wherein the shaft is autoclavable.

11. The system of claim 1, further comprising a control module coupled to a proximal end of the shaft.

12. The system of claim 11, wherein the control module is detachably coupled to the proximal end of the shaft.

13. The system of claim 11, wherein the control module is sterilizable.

14. The system of claim 13, wherein the control module is autoclavable.

15. The system of claim 11, wherein the control module includes a video processor.

16. The system of claim 15, wherein the shaft includes a data transfer cable, and wherein the image data received by the image capture device is transmitted via the data transfer cable to the video processor.

17. The system of claim 15, further comprising a wireless arrangement configured to transfer image data received by the image capture device to the video processor.

18. The system of claim 11, further comprising a display screen.

19. The system of claim 18, wherein the display screen is integrally mounted to the control module.

20. The system of claim 11, wherein the shaft includes an irrigation/aspiration channel, and wherein the control module includes an irrigation/aspiration system for conveying fluid through the irrigation/aspiration channel of the shaft.

21. The system of claim 11, wherein the shaft includes steering cables for steering at least a portion of the shaft, and wherein a power module includes steering motors connected to the steering cables.

22. The system of claim 11, wherein the shaft includes a working channel for permitting the passage of tools through the shaft.

23. The system of claim 11, wherein the control module includes a control unit for enabling a user to control the surgical system.

24. The system of claim 11, wherein the control module includes a controller for automatically controlling the surgical system.

25. The system of claim 11, further comprising a power module coupled to the control module, the power module configured to provide power to components housed in at least one of the control module and the shaft.

26. The system of claim 25, wherein, when the power module is configured to provide power to components housed in the shaft, the shaft includes a power transfer cable.

27. The system of claim 25, wherein the power module includes at least one of drive motors and a power source.

28. The system of claim 1, wherein the shaft is sized and configured for proctoscopic or anoscopic insertion into a patient's body.

29. A surgical system comprising:

a shaft having a distal end and a proximal end, wherein an interior of the shaft has a fluid-tight seal from the environment at the distal end and the proximal end so as to be sterilizable for re-use;

an image capture device configured to receive image data from the distal end of the shaft; and

a light-emitting diode configured to provide light at the distal end of the shaft,

wherein the image capture device and the light-emitting diode are mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use.

30. The system of claim 29, wherein the shaft is autoclavable.

31. The system of claim 29, wherein the shaft is sized and configured for endoscopic insertion into a patient's body.

32. The system of claim 29, wherein the shaft is flexible.

34. The system of claim 29, wherein the light-emitting diode is part of an array of light-emitting diodes.

36. The system of claim 29, wherein the light-emitting diode, the image capture device and the shaft are, as a unit, at least one of sterilizable and autoclavable.

37. The system of claim 29, wherein the image capture device is one of a camera and a CCD.

38. The system of claim 29, further comprising a power source for providing power to the light-emitting diode, the power source located at the distal end of the shaft.

39. The system of claim 29, further comprising a control module coupled to a proximal end of the shaft.

40. The system of claim 39, wherein the control module is detachably coupled to the proximal end of the shaft.

41. The system of claim 39, wherein the control module is sterilizable.

42. The system of claim 41, wherein the control module is autoclavable.

43. The system of claim 29, wherein the control module includes a video processor.

44. The system of claim 43, wherein the shaft includes a data transfer cable, and wherein the image data received by the image capture device is transmitted via the data transfer cable to the video processor.

45. The system of claim 44, further comprising a display screen.

46. The system of claim 45, wherein the display screen is integrally mounted to the control module.

47. The system of claim 39, wherein the shaft includes an irrigation/aspiration channel, and wherein the control module includes an irrigation/aspiration system for conveying fluid through the irrigation/aspiration channel of the shaft.

48. The system of claim 39, wherein the shaft includes steering cables for steering at least a portion of the shaft, and wherein the power module includes steering motors connected to the steering cables.

49. The system of claim 39, wherein the shaft includes a working channel for permitting the passage of tools through the shaft.

50. The system of claim 39, wherein the control module includes a control unit for enabling a user to control the surgical system.

51. The system of claim 39, wherein the control module includes a controller for automatically controlling the surgical system.

52. The system of claim 39, further comprising a power module coupled to the control module, the power module configured to provide power to components housed in at least one of the control module and the shaft.

53. The system of claim 52, wherein, when the power module is configured to provide power to components housed in the shaft, the shaft includes a power transfer cable.

54. The system of claim 52, wherein the power module includes at least one of drive motors and a power source.

55. The system of claim 29, wherein the shaft is sized and configured for proctoscopic or anoscopic insertion into a patient's body.

56. A surgical system comprising:

a shaft having a proximal end and a distal end, wherein an interior of the shaft has a fluid-tight seal from the environment at the proximal and at the distal end so as to be sterilizable for re-use;

an image capture device configured to receive image data from the distal end of the shaft;

a light-emitting diode configured to provide light at the distal end of the shaft;

a control module coupled to the proximal end of the shaft;

a power module coupled to the control module, the power module configured to drive at least one drivable component housed in at least one of the shaft, the control module and the power module; and

at least one power source integrally housed in at least one of the shaft, the control module and the power module,

wherein the image capture device and the light-emitting diode are mounted at the distal end of the shaft and fluid-tightly sealed from the environment by the shaft so as to be sterilizable for re-use.

57. The system of claim 56, wherein the shaft is sized and configured for endoscopic insertion into a patient's body.

58. The system of claim 56, wherein the shaft is flexible.

60. The system of claim 56, wherein the shaft is autoclavable.

61. The system of claim 56, wherein the control module is sterilizable.

62. The system of claim 61, wherein the control module is autoclavable.

63. The system of claim 56, wherein the light-emitting diode, the image capture device and the shaft are sterilizable as a unit.

64. The system of claim 63, wherein the light-emitting diode, the image capture device and the shaft are autoclavable as a unit.

66. The system of claim 56, wherein the light-emitting diode is part of an array of light emitting diodes.

67. The system of claim 56, further comprising a second power source for providing power to the light-emitting diode, the light-emitting diode and the second power source located at the distal end of the shaft.

68. The system of claim 56, wherein the control module is detachably coupled to the proximal end of the shaft.

69. The system of claim 56, wherein the control module includes a video processor.

70. The system of claim 69, wherein the shaft includes a data transfer cable, and wherein the image data received by the image capture device is transmitted via the data transfer cable to the video processor.

71. The system of claim 56, further comprising a display screen.

72. The system of claim 71, wherein the display screen is integrally mounted to the control module.

73. The system of claim 56, wherein the shaft includes an irrigation/aspiration channel, and wherein the control module includes an irrigation/aspiration system for conveying fluid through the irrigation/aspiration channel of the shaft.

74. The system of claim 73, wherein the power module includes a pump connected to an irrigation/aspiration system for at least one of introducing or removing fluid via the irrigation/aspiration channel.

75. The system of claim 56, wherein the shaft includes steering cables for steering at least a portion of the shaft, and wherein the power module includes steering motors connected to the steering cables.

76. The system of claim 56, wherein the shaft includes a working channel for permitting the passage of tools through the shaft.

77. The system of claim 56, wherein the control module includes a control unit for enabling a user to control the surgical system.

78. The system of claim 56, wherein the control module includes a controller for automatically controlling the surgical system.

79. The system of claim 56, wherein the shaft includes a power transfer cable.

80. The system of claim 56, wherein the surgical system is configured as a hand-held device.

81. The system of claim 56, wherein the power module includes at least one of drive motors and a power source.

82. The system of claim 56, wherein the shaft is sized and configured for proctoscopic or anoscopic insertion into a patient's body.

EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§1.130, 1.131, or 1.132. No other evidence has been entered by the Examiner or relied upon by Appellant in the appeal.

RELATED PROCEEDINGS APPENDIX

As indicated above in Section 2 of this Appeal Brief, "[t]here are no other prior or pending appeals, interferences or judicial proceedings known by the undersigned, or believed by the undersigned to be known to Appellant or the assignee, POWER MEDICAL INTERVENTIONS, INC., 'which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.'" As such, there are no "decisions rendered by a court or the Board in any proceeding identified pursuant to [37 C.F.R. § 41.37(c)(1)(ii)]" to be submitted.